U.S. Pharmacopeia
The Standard of Quality℠

June 21, 2004

Dockets Management Branch
HFA-305
Food and Drug Administration
5600 Fishers Lane, Room 1061
Rockville, Maryland 20857

Re: Docket No. 2004N-0221

Dear Sir/Madam:

USP is submitting comments to the FDA for the *Medicare Prescription Drug Improvement and Modernization Act of 2003; Study on Making Prescription Pharmaceutical Information Accessible for Blind and Visually-Impaired Individuals*. Specifically, USP is providing information associating medication errors with blindness and visual impairment for consideration of the types of errors most common in this population.

USP is providing information reported to its two medication errors reporting programs, the USP-ISMP Medication Errors Reporting (MER) Program and MEDMARX℠. Because neither database has codes specific to blindness or visual impairment, reports were identified by general text-querying methods which search by text strings like "vision" or " *blind* ". The queries produced 13 reports from the MER Program and 4 reports from MEDMARX involving patients with colorblindness, poor vision, or loss of sight. USP also has a large number of reports involving medications or syringes that look so similar that the products have been confused, or are likely to be confused. Often these errors are caught before the medication is used because of an alert, inquiring patient with good vision. If the patient had any loss of vision, it is possible the medication error might not have been averted. If FDA is interested in receiving such reports, USP will be happy to provide them.

Thank you for this opportunity to provide information to the docket. If you have questions, please contact me at 301-816-8215 or ddc@usp.org.

Sincerely,

Diane D. Cousins, RPh
Vice President
Center for the Advancement of
Patient Safety

cc: Yana Mille
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Enclosures

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MEDMARX[SM]

MEDMARX Records Reporting Adverse Medication Events Involving the Visually Impaired or Blind*

For the Period of
8/1/1998 Through June 15, 2004
n = 4

6/21/2004

Report #: 1

Date entered: 10/3/01

Rpt category: C

Description:
Patient in home cared for by a blind family member, gave wrong dose of morphine. Supposed to give 15mg tablets but gave 30mg sustained release.

Node: Administering

Location Patient home/residence

Staff (Initial error): Patient/Family Member/Caregiver

Generic Name: Morphine

Type of Error:	Cause of Error:	Contributing Factors:	Actions Taken:
Improper dose/quantity		Data not provided	Informed patient/caregiver of medication error

Patient Age:		Level of care as result of error	Patient Outcome Detail
67	Years	None	

* This report includes data as reported by participating facilities.

6/21/2004

Report #: 2

Date entered: 2/8/02

Rpt category: C

Description:
Found K-dur tab on floor beside patient's bed. Patient is blind and nurse put med in patient's mouth and gave water. Did not realize that the patient had not swallowed.

Node: Administering

Staff (Initial error): Nurse, Registered

Location Nursing (Patient Care) Unit

Generic Name: Data Not Provided

Type of Error:	Cause of Error:	Contributing Factors:	Actions Taken:
Omission error		Data not provided	

Patient Age: 0 Hours

Level of care as result of error
Data not provided

Patient Outcome Detail

MEDMARX[SM]

MEDMARX Records Reporting Adverse Medication Events Involving the Visually Impaired or Blind*

For the Period of
8/1/1998 Through June 15, 2004
n = 4

6/21/2004

Report #: 3

Date entered: 7/2/02

Rpt category: E

Description:
Patient on morphine PCA developed respiration insufficiency and metabolic & respiratory alkalosis. Continuous infusion ordered to be dc'd 6/18, but according to records was continued. Xanax added 6/18 PM, RR at 8 at 0615 on 6/19. Narcan given and PCA stopped (reported that family was pushing PCA button; patient blind and on dialysis).

Node: Administering

Staff (Initial error): Nurse, Registered

Location Data not provided

Generic Name: Morphine

Type of Error:	Cause of Error:	Contributing Factors:	Actions Taken:
Extra dose	Dispensing device involved Performance (human) deficit Procedure/protocol not followed	Data not provided	Education/Training provided

Patient Age: 40 Years

Level of care as result of error
Drug therapy initiated/changed
Laboratory tests performed
Observation initiated/increased
Vital signs monitoring initiated/increased

Patient Outcome Detail
Narcan, sod. bicarb. given; ABGs monitored.

* This report includes data as reported by participating facilities.

MEDMARX[SM]

MEDMARX Records Reporting Adverse Medication Events Involving the Visually Impaired or Blind*

For the Period of
8/1/1998 Through June 15, 2004
n = 4

6/21/2004

Report #: 4

Date entered: 2/6/03

Rpt category: C

Description:
An outpatient at home with poor vision had mixed up her tablets from two bottles of different strengths of furosemide (?? Doses)

Node: Administering

Location Patient home/residence

Staff (Initial error): Patient/Family Member/Caregiver

Generic Name: Furosemide

Type of Error:	Cause of Error:	Contributing Factors:	Actions Taken:
Improper dose/quantity	Brand/generic names look alike	None	

Patient Age: 70 Years

Level of care as result of error
None

Patient Outcome Detail

* This report includes data as reported by participating facilities.

"*blind* or *visual* or *vision* or *sight* or *impair* in the following fields: **Error Description** or **Outcome** or **Recommendations**

Includes records received through the USP-ISMP Medication Errors Reporting (MER) Database
Between 1/16/1992 and 4/9/2004

Access Number	Date Received By USP	Error Description	Outcome	Recommendations
041401	4/13/1995	THE REPORTER IS AWARE OF SEVERAL INCIDENTS A YEAR WHERE DIABETIC PATIENTS EXPERIENCE PROBLEMS BECAUSE THE WRONG VIAL OF INSULIN IS USED. THE SIMILARITY OF THE LABELS OF NOVOLIN R AND NOVOLIN N PLUS POOR EYESIGHT CONTRIBUTE TO THE ERRORS. THE MEDICATION WAS ADMINISTERED TO OR USED BY THE PATIENT. THE ERRORS OCCURRED IN THE PATIENTS' HOMES.	Problems	The reporter recommends to change the color of the label; use blue for NPH and red for Regular Insulin.
041566	8/11/1995	AN ELDERLY FEMALE CAME INTO THE PHARMACY WITH TWO CONTAINERS OF HER MEDICATIONS. GENERIC NADOLOL CLOSELY RESEMBLES LANOXIN IN COLOR AND SHAPE. BECAUSE OF VISION PROBLEMS, SHE COULD NOT DISTINGUISH BETWEEN THE TWO DRUGS AND REQUESTED THE PHARMACIST'S ASSISTANCE. THE POTENTIAL ERROR WAS DISCOVERED WHEN THE PATIENT CAME INTO THE PHARMACY ON AUGUST 10, 1995. THIS OCCURRED IN A RETAIL PHARMACY. PATIENT COUNSELING WAS PROVIDED.		
042060	8/27/1996	A physician wrote a prescription for Lactinex one capsule four times a day for one week and told the patient, an 84-year-old female, to get it at a health food store. The physician wrote the "1" as an apothecary symbol and a clerk made a wrong interpretation and mistakenly read the "1" as a "7." The clerk told the patient to take seven (7) capsules four times a day. Because she is legally blind, the patient asked the clerk to write out how she should take the medication in large block letters with a felt tip	Severe diarrhea and dehydration	

Access Number	Date Received By USP	Error Description	Outcome	Recommendations
		pen. The patient took 28 capsules for two days becoming terribly ill with severe diarrhea and dehydration.		
042120	10/11/1996	An endocrinologist reported that two of his patients, who had been prescribed Humalog and Humulin N, confused the two insulins, injecting Humulin N instead of Humalog. The two patients, who were elderly with poor eyesight, developed hypoglycemia. The physician has switched the patients from Humulin N to a Squibb product so that the patients will not confuse the two insulins.	Patients developed hypoglycemia	The label on the Humalog should be quite different from the other Lilly insulin products or, as this physician did, use two different brands.
050308	7/10/1997	The reporting pharmacist was alerted to the problem by a patient complaint. The patient brought to her attention that the tablet shapes of Monopril and Levoxyl are very similar and one could easily be mistaken for the other. Because of her poor eyesight, the patient told the reporter that this is very problematic and a constant source of worry. The patient hopes this report may provoke a change in tablet shape by either manufacturer in hopes of promoting good health. Also, the reporter stated that the color of the tablets is similar; Levoxyl is light beige in color and Monopril is white.		The shape of the Monopril tablet should be changed.
051460	6/29/1998	Pharmacy technician incorrectly prepared 20 pre-filled insulin syringes. The technician filled each syringe with 100 units of NPH insulin instead of the prescribed 15 units. Pharmacist did not verify the prescription for accuracy. The patient, who is legally blind, realized by the feel of the syringe that the dosage was not correct and waited until someone else could verify the dosage prior to administration of the insulin. CI 96 14121	N/I	The pharmacist should always verify the work of a technician for accuracy.
053534	12/7/2000	Staff from the forensic institute came down with two bottles of medication. One bottle contained Parke-Davis brand Dilantin Kapseals 100 mg and the other had Parke-Davis's Celontin Kapseals 300 mg. Amazed that the FDA would allow Parke-Davis to market two products that looked so much alike. Aside from the difference in size, the two products look alike. For an		

Access Number	Date Received By USP	Error Description	Outcome	Recommendations
		elderly and visually impaired patient, those medications could certainly be confusing and could be a set up for a problem.		
053547	12/18/2000	A patient almost choked because he swallowed a capsule desiccant instead of a cardiac medication. The patient has poor eye sight, poured out the capsule onto his hand, and then swallowed the medication.	The patient choked and gagged, but was able to get the desiccant out.	Pharmacists should counsel patients about desiccants and, if possible, remove them from the drug containers before dispensing.
053748	2/14/2001	The package labels of Betapace manufactured by Berlex and Sotalol manufactured by Par are identical in layout and color. Granted, the trade name item has the strength embossed on the tablets, but good near vision is essential.		
054314	8/21/2001	Recently a patient was admitted to the reporter's facility for an orthopedic problem. The medical history of the patient included glaucoma and diabetes. The pharmacy received several medication orders for his glaucoma and diabetes including one for "Glucose Control Solution one drop to left eye twice daily" written by the orthopedic physician assistant. When the pharmacist questioned the prescriber she was told, "That's what the patient says he uses," so the pharmacist asked the patient who, indeed, did confirm that he was instilling the drops in his eye per his eye doctor's instructions. When the eye doctor was contacted it was determined that the correct medication was supposed to be Timolol 0.5%. Both products, Glucose Control Solution by Precision and generic, as well as, brand name Timolol ophthalmic solution are small dropper bottles with yellow caps and small black lettering. This elderly diabetic patient with poor eye sight confused the Timolol with the Glucose Control Solution.		
054396	9/18/2001	Source: The Sun in Howard, February 11, 2001. The patient presented prescriptions for both Coumadin and Lipitor. The patient and his wife say the pharmacist filled both prescription bottles with Coumadin. Before they noticed that both bottles might have contained Coumadin, the patient had received a cut	The patient was taken to the hospital.	

Access Number	Date Received By USP	Error Description	Outcome	Recommendations
		and noticed that it wouldn't stop bleeding. The error was discovered when the patient spilled the bottles and called his wife to help him separate the tablets. She could not tell them apart. "They all looked the same color," she said. "They're shaped exactly the same." She says the two medications he should have received are similarly shaped and colored; Coumadin is salmon colored and Lipitor is white. She stated that her husband would not be able to distinguish between the tablets because he is colorblind. The pharmacy denies that the two tablets are approximately the same shape and color, and that both bottles contained Coumadin. Upon discovering that the patient had apparently been taking a double dose of Coumadin for several days, the patient's wife called her husband's physician who told her to take him to a hospital. She also notified the pharmacy.		
055014	5/15/2002	Maybe you have alerted us to this problem and I forgot, but I want to report inadequate labeling on plastic vials of medication for inhalation by Nephron Pharm Corp. The two specific products that we have at a medical center are Ipratroprium Bromide inhalation solution 0.5 mg per 2.5 mL and Albuterol Sulfate inhalation solution for inhalation 2.5 mg in 3 mL. The unit dose package is a clear, plastic "bullet" with raised lettering and no color or attached label. The most distinguishing feature is a raised "I" or "A" on the tear-off-tab part of the vial. They are about 0.25 inches different length. In a room with less than ideal light or less than ideal eyesight, the two packages look identical. We have no reports of errors here but are concerned and are reviewing our options. The manufacturer should add some color and/or opaque labeling with black lettering.		
055543	1/23/2003	I work in a cardiology office and saw a small pamphlet announcing the new Lotrel 10/20 mg dose to prescribers. The picture of the product looks almost identical to Nexium 40 mg. Nexium capsules are smaller and have three stripes rather than		Capsule color change to the Lotrel could potentially prevent confusing the two drugs.

Access Number	Date Received By USP	Error Description	Outcome	Recommendations
		two. However, the similarities were striking to me, and I could see confusing the two, especially since these two drugs are often prescribed to the elderly, a population generally with poorer eyesight.		